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**London W1M 8AH (GB)**(54) **Product for assisting a smoker in giving-up the habit.**

(57) A product for assisting a smoker in giving-up the smoking habit consists of at least three and preferably four pump operated aerosol cans. Each can, apart from one, contains nicotine in liquid form dispersed in at least one pharmaceutically acceptable carrier. The cans which contain nicotine have differing quantities of nicotine in them. Pharmaceutically acceptable carriers are alcohol, a flavouring, glycerine and saccharine. The volume of alcohol and glycerine increases as the percentage of nicotine decreases. The can which does not contain nicotine merely comprises one or more pharmaceutically acceptable substances.

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FIELD OF THE INVENTION

THIS INVENTION relates to a product for assisting a smoker in giving-up the smoking habit.

5 BACKGROUND TO THE INVENTION

Cigarette smoke contains a large number of very complex substances the most important of which is nicotine, this being the substance to which cigarette smokers develop an addiction. Upon a cigarette smoker ceasing to smoke, withdrawal symptoms and a craving for a cigarette occur which result from the body's need for nicotine. To alleviate the effect of these withdrawal symptoms and the craving for a cigarette it has been proposed that the person attempting to break the smoking habit should be given decreasing doses of nicotine. This enables the nicotine level in the body to be reduced over a period of time which results in the withdrawal symptoms being less severe. Chewing gum with nicotine in it and tablets containing nicotine have been marketed. More recently pads which are applied to the skin have become available. Pads of various sizes are provided, the pads containing nicotine. The nicotine is absorbed steadily through the skin. The concept is that a large pad is used initially when the person attempting to give-up the smoking habit requires a high level of nicotine in his or her body to prevent withdrawal symptoms. Pads of progressively decreasing size are used as the body becomes less dependant on nicotine. In this regard reference is made to US patent 4920989 which discloses such pads.

The concept of inhaling nicotine from an aerosol device is also known and reference can be made to US Patents 4813437 and 4945929. The purpose of such devices is to provide the user with the nicotine that his or her body requires without smoke, tars and other harmful substances found in cigarettes simultaneously being inhaled. Thus the known aerosol products are substitutes for cigarettes and do not assist a smoker in ridding himself or herself of nicotine addiction. Nicotine addiction is the main reason why giving up the smoking habit is so difficult.

OBJECT OF THE INVENTION

The object of the present invention is to provide as efficacious product for assisting a person in giving-up the smoking habit.

BRIEF SUMMARY OF THE INVENTION

According to the present invention there is provided a plurality of containers each of which, apart from one, contains nicotine in liquid form dispersed in at least one pharmaceutically acceptable carrier, the percentage of nicotine by volume in each container being different to the percentage of nicotine in each other container, and said one container having therein said pharmaceutically acceptable carrier but no nicotine.

The nicotine should not constitute more than 2% by volume of the contents of the container.

There should be at least three containers, two containers having nicotine therein with the percentage of nicotine in one of these containers being greater than the percentage of nicotine in the other of these containers, the third container containing said pharmaceutically acceptable carrier but no nicotine.

It is preferred that there be four containers, three containers having nicotine therein with the percentage of nicotine in each of these containers being different to the percentage in each of the others of these three containers, the fourth container having therein at least one pharmaceutically acceptable carrier but no nicotine:

The containers can contain about 1.5%, about 1.0%, about 0.5% and 0.0% by volume nicotine. By way of example, the percentage of nicotine in the three containers can be 1.45%, 0.97% and 0.48%. Experimentation has shown that four containers containing these volumes of nicotine provides a suitable treatment for a person smoking about 30 cigarettes per day.

The containers are preferably pump operated aerosol cans so that depressing the plunger once dispenses a predetermined volume of liquid from the can. This minimises the risk that the person may receive too heavy a dose which can occur if an aerosol can of the type which contains a propellant under pressure is used.

Suitable pharmaceutically acceptable liquid carriers are alcohol, glycerine, saccharine and a flavouring such as peppermint. The alcohol can occupy the greatest volume eg from 75% to 85%, the volume of alcohol increasing as the percentage of nicotine decreases. There can be between 10- and 20% glycerine, the volume of glycerine increasing as the volume of nicotine decreases. The peppermint flavour can be about 4% by volume and the saccharine a trace eg 0.1% by volume.

## DETAILED DESCRIPTION      THE INVENTION

The following table sets out the ingredients of four cans each having a volume of 20ml and the nicotine content of which ranges from 1.45% to 0% and which is suitable for the treatment, over a period of about 1 month, of a person who at the beginning of treatment is smoking about 30 cigarettes per day.

	Can 1	Can 2	Can 3	Can 4
Nicotine	1.45	0.97	0.48	0.00
Alcohol	79.71	80.10	80.49	80.88
Saccharine	0.12	0.12	0.12	0.12
Glycerine	14.78	14.85	14.93	15.00
Peppermint Flavour	3.94	3.96	3.98	4.00

All figures are percentages by volume.

The person wishing to give up smoking, upon feeling the need for a cigarette, takes the can which contains most nicotine and, in the way that breath fresheners are used, sprays into his or her mouth. One depression of the plunger is sufficient to dispense a suitable amount of liquid in atomized form. The first can is used each time that the person feels like smoking a cigarette until it is exhausted. The second aerosol can is then used in the same way and it will be understood that the person is, immediately the second can is brought into use, receiving a smaller dose of nicotine per depression of the pump than was being received during use of the first can. Thus while nicotine is still being provided, the amount provided has been decreased. Once the second can has been depleted the third can is brought into use and subsequently the fourth can which has therein no nicotine whatsoever. Thus the nicotine level of the patient is decreased gradually and the effects of a sudden reduction in the nicotine level in the body are avoided.

Whilst it is preferred that the nicotine be in a pump actuated aerosol can, it is possible for it to be in a bottle for application by medicine measure or by dropper or in a deformable squeeze bottle with a nozzle, such bottles currently being used, for example, to apply nasal sprays.

### Claims

1. A plurality of containers each of which, apart from one, contains nicotine in liquid form dispersed in at least one pharmaceutically acceptable carrier, the percentage of nicotine by volume in each container being different to the percentage of nicotine in each other container, and said one container having therein said pharmaceutically acceptable carrier but no nicotine.
2. A plurality of containers according to claim 1, the number of containers being three, two containers having nicotine therein with the percentage of nicotine in one of these containers being greater than the percentage of nicotine in the other of these containers, the third container containing said pharmaceutically acceptable carrier but no nicotine.
3. A plurality of containers according to claim 1, the number of containers being four, three containers having nicotine therein with the percentage of nicotine in each of these containers being different to the percentage in each of the others of these three containers, the fourth container having therein at least one pharmaceutically acceptable carrier but no nicotine.
4. A plurality of containers according to claim 3, wherein the percentage of nicotine in said three containers is respectively about 1.5%, about 1% and about 0.5%.
5. A plurality of containers according to Claim 3, wherein the percentage of nicotine in said three containers is respectively 1.45%, 0.97% and 0.48%.
6. A plurality of containers according to any one of Claims 1 to 5 and which are pump operated aerosol containers.

7. A plurality of containers according to any one of Claims 1 to 5 for sequential use in the treatment of nicotine addiction.

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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	GB-A-2 191 718 (BRITISH-AMERICAN TOBACCO COMPANY LTD.) * abstract; claims 1,2; figure 1 * & US-A-4 945 929 ---	1-7	A24F47/00
A	US-A-4 284 089 (RAY) * column 3, line 53 - column 4, line 5; claims 1,2,5; figure 1 * ---	1-7	
A	EP-A-0 307 118 (INVENTOR'S FUNDING COMPANY LTD.) * column 2, line 53 - column 3, line 19; claims 1,5,7; figure 1 * ---	1-7	
A	WO-A-9 118 636 (KABI PHARMACIA AB) * page 6, line 23 - line 33; claim 1; figures 1,2 * -----	1-7	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A61M A24F
The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 25 MAY 1993	Examiner MICHELS N.
<b>CATEGORY OF CITED DOCUMENTS</b>			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document	